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| 10/597,436 | 08/22/2008 | Sylvie Pridmore-Merten | 3712036.00745 | 1948 | |
| 29157 | 7590 | 01/04/2012 | EXAMINER | | |
| K&L Gates LLP | | HOBBS, LISA JOE | | | |
| P.O. Box 1135 | | ART UNIT | | PAPER NUMBER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

| | | |
|------------------------------|------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/597,436 | PRIDMORE-MERTEN, SYLVIE |
| | Examiner | Art Unit |
| | Lisa J. Hobbs | 1657 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 September 2011.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 1-8, 12-16, 18-21, 31-33, 35-37, 39 and 40 is/are pending in the application.
 - 5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1-8, 12-16, 18-21, 31-33, 35-37, 39 and 40 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Status

Claims 1-8, 12-16, 18-21, 31-33, 35-37, 39-40 are active in the case. Claims 1-8, 12-16, 18-21, 31-33, 35-37, 39-40 are under examination; no claims are withdrawn as drawn to a non-elected invention. Claims 9-11, 22-30, 34 and 38 have been cancelled by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 12-16, 18-21, 31-33, 35-37, 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Simone (US 6,380,252 A), Cavazza (US 6,063,820 A and 6,348,495 A), Hamilton (US 2002/ 077349 A and 2003/060503 A), Germano (US 6,503,506 A), and Kosbab (US 2001/0031744 A1), in view of Murad (US 20030224071 A1), .

De Simone teaches “[a] method is provided for increasing the levels of IGF-1 for the therapeutic treatment or prophylaxis of cytological disorders or diseases related to IGF-1 selected from the group including neuropathies of the optic nerve and of the olfactory nerve, neuralgia of the trigmeninal nerve, Bell's paralysis, amyotrophic lateral sclerosis, osteoporosis, anthropathy, arthritis, cervical spondylosis and hernia of the intervertebral discs clinical syndromes of reduced height, cachexia and acute or chronic hepatic necrosis, Turner's syndrome, sarcopenia, growth hormone insensitivity syndromes, obesity, asthenia, myasthenia and heart asthenia, immunodeficiencies and reperfusion injuries, and for the cicatrization of wounds, the healing of ulcers, the treatment of burns, tissue regeneration, cutaneous, intestinal and hepatic tissue regeneration and the formation of dentine, that includes administering, to a patient in need thereof, at least one selected from the group including L-acetylcarnitine, L-isovalerylcarnitine, and L-propionylcarnitine or pharmacologically acceptable salts thereof. The present invention also relates to a method and composition for treating HCV and/or increasing the levels of IGF-1 of a patient in need thereof, the composition including at least one selected from the group including L-acetylcarnitine, L-isovalerylcarnitine, L-propionylcarnitine and pharmacologically

acceptable salts thereof and mixtures thereof; and at least one selected from the group including L -carnitine, coenzyme Q10, vitamin E and Se-L-methionine and pharmaceutically acceptable salts and derivatives thereof and mixtures thereof" (abstract).

Cavazza ('495) teaches "[a] medical food for diabetics is disclosed which comprises as characterizing active ingredients .gamma.-linolenic acid and at least one alkanoyl-L -carnitine, e.g. acetyl-L -carnitine and/or propionyl-L -carnitine" (abstract) and that "[a]n object of the present invention is to provide a medical food for diabetics which enables them to compensate for the reduced metabolism of essential fatty acids typical of such subjects. In particular, the object of the present invention is to provide a medical food of this type which makes it possible to by-pass the enzyme blockade caused by the reduced activity of omega-6-desaturase which occurs in diabetics and gives rise to inadequate conversion of linoleic acid into y-linolenic acid and thus to a reduced production of prostaglandin and leukotriene precursors (BSUM paragraph 17). Also taught (Cavazza '820) is "a new therapeutic use of the lower alkanoyl L-carnitines and their pharmacologically acceptable salts to produce pharmaceutical compositions for the treatment of chronic intestinal disorders, in particular inflammatory bowel diseases, more particularly, ulcerative colitis or celiac disease" (BSUM paragraph 1).

Cavazza ('495) teaches at Example 2: "S.C., male, 20 years old, height 178 cm, weight 69 Kg. Regularly born, he was breast-fed by her mother for about 40 days. At about 9 months diarrhoea and meteorism appeared, lasting one month. Regular growth and sexual development. Measles. In 1995 a blister dermatitis appeared, with strong itching. After different hypotheses, a Duhring dermatitis was diagnosed. An EGDS was carried out with biopsies reporting celiac disease. A rigid gluten-free diet started. Dermatitis was resolved, but still 2-3 daily discharges,

with poorly formed faeces and abdominal pains were reported. The patient started the treatment with propionyl L -carnitine (2 grams/day orally for two months), with an improvement of the general symptomatology. After 4 months the patient started sporting activity again”.

Hamilton (2002) teaches “methods to treat age-related vision losses. The method comprises administering a combination of a carnitine and an oxidant. Preferably the oxidant is thioctic acid. Preferably 0.12 grams to 3 grams of carnitine (particularly ALC) and 0.12 and 1.5 grams of R-.alpha.-lipoic acid are administered. Optionally, coenzyme Q and/or creatine also are administered. Preferably 10 mg to 500 mg/day of coenzyme Q10 and 1 to 30 grams/day of creatine are administered” (abstract). As well, Hamilton also teaches (2003) “compositions to meet the needs of aged pets and other animals. A pet food formulated for senior pets provides .alpha.-lipoic acid at about 0.15 to 50 mg/kg body weight/day, carnitine at about 0.5 to 100 mg/kg/day, and optionally coenzyme Q at about 0.01 mg/kg/day and/or creatine at about 15 mg to about 1 g/kg/day. A pet treat for senior pets provides .alpha.-lipoic acid at about 0.15 to 50 mg/kg body weight/day, carnitine at about 0.5 to 100 mg/kg/day, and optionally coenzyme Q at about 0.01 mg/kg/day and/or creatine at about 15 mg to about 1 g/kg/day. A pet supplement for mature pets offers .alpha.-lipoic acid at about 0.15 to 50 mg/kg body weight/day, carnitine at about 0.5 to 100 mg/kg/day, and optionally coenzyme Q at about 0.01 mg/kg/day and/or creatine at about 15 mg to about 1 g/kg/day” (abstract).

Germano teaches “[a] nutritional supplement...for treating chronic debilitating diseases such as HIV/AIDS to overcome conditions of oxidative stress, decreased lean muscle mass, decreased energy production (mitochondrial failure) and support immune function. It comprises orally administrable superoxide dismutase (SOD), preferably SOD/GLIADIN, in combination

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with other antioxidant/immune support components (Beta Glucans, Nucleotides, Fruit Polyphenols); High Immunoglobin Whey; (undenatured whey), Ornithine alpha ketoglutarate (OKG), Branched Chain Amino Acids and Glutamine to reduce loss of lean muscle mass; and Coenzyme Q 10, D-Ribose and L-Carnitine to provide energy support (decrease mitochondrial failure).

Kosbab teaches “nutrient and therapeutic compositions for treatment and prevention of symptoms and disease conditions associated with microangiopathy and macroangiopathy and to methods using the compositions. In particular, the invention relates to compositions useful in the treatment of diabetic retinopathy and nephropathy, to compositions useful in the treatment of other retinal disorders including macular degeneration and cataracts, to compositions useful in wound healing, to compositions useful for treatment and prevention of neuropathy, to compositions useful for treatment and prevention of cardiovascular disease and to compositions useful for the treatment and prevention of dental and periodontal disorders” and that “[v]ascular degeneration is directly associated with cardiovascular disease, atherosclerosis and plaque deposition and indirectly associated with degenerative conditions of the retina (including retinopathy), kidney (nephropathy) and nervous system (neuropathy), as well as skin ulcers” [0003].

He also teaches that “L -Carnitine is an essential co-factor of fatty acid metabolism. Significantly decreased plasma carnitine levels are common in insulin dependent diabetics including those with nephropathies. This implies that such patients may suffer from inadequate ATP reserves that could cause fatigue and oxidative stress due to reduced lipid metabolism caused by faulty transport of fatty acids across mitochondrial membranes. Carnitine

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supplementation supports increases in fat utilization and oxygen uptake while decreasing plasma lactate levels and respiratory quotients. Carnitine has been shown to reduce ketones, LDL and triglycerides and increase HDL while acting as a vasodilator. Low carnitine levels may correlate with low plasma albumin and edema. L -Carnitine can be provided as N-acetyl-L -carnitine hydrochloride, the preferred form for this invention. Carnitine can be also be provided as the L- or D,L-form as hydrochloride or other salts" [0453].

Murad et al. teach an "invention [that] relates to compositions and methods for managing connective tissue disorders in a patient, a sugar compound that is converted to a glycosaminoglycan, a primary antioxidant component, at least one amino acid component, at least one transition metal component, at least one moisturizing agent, at least one fatty acid" [abstract}], primarily via topical administration, but also that "[o]ther moisturizing agents that hydrate the skin and connective tissue and are useful in the compositions and methods of the present invention include, but are not limited to, panthenol; primrose oil; GLA 3 and other fish oils that may include, for example, the omega-3 and omega-6 oils; and flax seed oil. Preferably, these moisturizing agents are administered orally" [0056, claim 3]. They teach that various components, including vitamins and grape seed oil, are beneficial for the skin of a patient suffering from various skin ailments, and that vitamin ingestion should be monitored when being administered orally to be sure that over dosage does not occur [0067].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De Simone, Cavazza, Hamilton, Germano and Kosbab to achieve the invention as recited. One would be motivated to do so in order to develop non-invasive treatments, especially treatments that would be part of a daily schedule such as food, for

various medical problems as outlined in the prior art. One would have a reasonable expectation of success since the medically oriented foodstuffs and compositions taught also comprise the natural compounds, such as isoprenoids, terpenes, ginkgo biloba, etc., disclosed in the instant claims.

Response to Arguments

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claimed invention is patentable over the prior art because the claimed invention is ingestible and that each of the prior art formulations cited do not teach stimulating lipid metabolism with the result of ameliorating skin disorders. Applicant argues that Murad et al. is structurally distinct from the claimed composition because the reference composition does not contain L-carnitine or grape seed extract. Thus, Murad et al.'s composition would not produce the same effects on the body as recited in the claims. However, the rejection is based on the compositions and methods of administration taught by the combination of prior art available to one skilled in the art of combining nutrients for beneficial effects, not on the composition of Murad et al. alone. The prior art as cited, taken together, teach compositions and methods with the same ingredients claimed by applicant. Thus, the composition taught by the references *is* structurally the same as the claimed composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim; from the prior art it is known that the compounds in the instant composition have effects on lipid metabolism and it is known that

stimulating lipid metabolism has multiple effects on the human body, including increased oil available to the skin. In addition, the fact that applicant has recognized other advantages which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Since the prior art provides motivation for the combination of the claimed ingredients and use in a method to accomplish what is known, increasing lipid metabolism by applying the composition, any advantages from this composition would be found in this prior art combination.

Applicant also argues that DeSimone et al. Cavazze et al., Hamilton et al., Germano et al. and Kosbab are non-analogous art because they are directed to various medical applications of the nutrients recited rather than specifically the intended use of the composition as currently claimed, increasing lipid metabolism, with the known side effect of ameliorating various skin conditions. However, as discussed in the previous Office action, the recited prior art is considered analogous art because it contains ingredients that overlap with applicant's claimed ingredients and is administered in the same amounts in the same methods of administration. In determining if a piece of prior art is analogous art, MPEP section 2141.01(a)(II) states that an overlap in structure and function shows that a reference is reasonably pertinent to the claimed invention. The prior art compositions have the named ingredients; thus, they clearly overlap in structure. Furthermore, Kosbab particularly is concerned with factors which affect fatty acid metabolism in the human body, specifically L-carnitine. This function overlaps with applicant's claimed intended use of producing effects on the skin via lipid metabolism. Therefore, the prior art is considered to be analogous.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, afternoons M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be

obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh